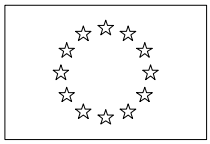

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16/11/2000

C(2000) 3239

**NOT FOR PUBLICATION**

# COMMISSION DECISION

of 16/11/2000

amending the marketing authorization for the
medicinal product
for human use

**"AZOPT – brinzolamide"**

(new pack size)

ONLY THE ENGLISH TEXT IS AUTHENTIC

(Text with EEA relevance)

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98,[2]

Having regard to Commission Regulation (EC) No 542/95[3] of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93, and in particular Article 5(2) thereof,

Having regard to the application to amend the marketing authorization issued by Commission Decision on 9 March 2000 concerning the medicinal product **"AZOPT – brinzolamide"** entered in the Community register of medicinal products under No EU/1/00/129/001-002, submitted on 20 March 2000 under Article 4(1) of the said Commission Regulation,

Having regard to the favourable opinion of the European Agency for the Evaluation of Medicinal Products, delivered on 5 April 2000 by the Committee for Proprietary Medicinal Products,

Whereas:
(1) medicinal product **"AZOPT – brinzolamide"** meets the requirements of Council Directives 65/65/EEC,[4] 75/318/EEC[5] and 75/319/EEC,[6] as last amended by Directive 93/39/EEC;[7]

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1 OJ No L 214, 24. 8. 1993, p. 1.
2 OJ No L 88, 24.3.1998, p. 7.
3 OJ L 55, 11.3.1995, p.15.

(2) the measures provided for in this Decision fall within the notification procedure applicable to minor variations as defined in Article 3(1)(a) of Commission Regulation (EC) No 542/95,

(3) in accordance with Article 5(2) of Commission Regulation (EC) No 542/95, this Decision shall take effect retroactively on the 31st day following receipt by the European Agency for the Evaluation of Medicinal Products of the application for a variation relating to it.

(4) Decision C(2000) 576 of 9 march 2000 authorising the placing on the market of the medicinal product **"AZOPT – brinzolamide "** should therefore be amended,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000) 576 is hereby amended as follows:

(a) - **Article 1 is completed by** :

EU/1/00/129/003 – AZOPT – 10 mg/ml - Eye drops, suspension - Ocular use - Bottle (LDPE) – 3 bottles (5ml)

(b) - Annex I (summary of product characteristics) is replaced by Annex I to this Decision;

(c) - Annex III (labelling and package leaflet) is replaced by Annex II to this Decision.

Article 2

This Decision shall apply from 21 April 2000.

Article 3

This Decision is addressed to Alcon Laboratories (UK) Ltd., Boundary Way, Hemel Hempstead, Herts HP2 7UD, United Kingdom.

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4 OJ 22, 9.2.1965, p. 369/65.

5 OJ L 147, 9.6.1975, p. 1.

6 OJ L 147, 9.6.1975, p. 13.

7 OJ L 214, 24.8.1993, p. 22.

Done at Brussels, 16/11/2000

For the Commission

Ekki LIIKANEN
Member of the Commission